

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in part of a filthy substance by reason of the presence of insect fragments and rotten and moldy plant material; and, Section 501 (a) (2), it had been prepared and packed under insanitary conditions whereby it may have become contaminated with filth.

Misbranding, Section 502 (b) (2), the article in the April 17, 1946, shipment failed to bear a label containing an accurate statement of the quantity of the contents, in that the label affixed to the bottle bore no statement of the quantity of the contents.

DISPOSITION: July 21, 1948. A plea of guilty having been entered, the court sentenced the defendant to serve 1 year and 1 day on each of the 3 counts of the information, with the sentence on each count to run concurrently. The sentence was suspended and the defendant was placed on probation for 1 year and 1 day.

2509. Adulteration of chamomile flowers. U. S. v. 35 Bags, etc. (F. D. C. No. 25089. Sample No. 9934-K.)

LIBEL FILED: July 14, 1948, Southern District of New York.

ALLEGED SHIPMENT: From the country of Hungary to New York, N. Y. The product was received in New York on May 15, 1947.

PRODUCT: 35 bags containing a total of 2,010 pounds and 34 cases containing a total of 3,967 pounds of *chamomile flowers* at New York, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: September 7, 1948, The Meer Corporation, New York, N. Y., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for cleaning, fumigating, and sifting, under the supervision of the Federal Security Agency.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

2510. Adulteration of triple distilled water, solution anterior pituitary, ovarian extract, and ampuls of sodium iodide. U. S. v. Torigian Laboratories, Inc., and John Torigian. Plea of guilty for corporation on all four counts and plea of guilty for individual on count 1. Fine of \$1,000 against corporation; individual fined \$800 on count 1 and placed on probation for two years. Counts 2, 3, and 4 against individual dismissed. (F. D. C. No. 17881. Sample Nos. 78856-F, 87034-F, 16512-H, 16514-H, 16520-H.)

INFORMATION FILED: March 17, 1947, Eastern District of New York, against the Torigian Laboratories, Inc., Queens Village, New York, N. Y., and John Torigian, president of the corporation.

ALLEGED SHIPMENT: On or about July 15, August 30, and December 12, 1944, and January 26, 1945, from the State of New York into the States of Michigan and Illinois.

NATURE OF CHARGE: *Triple distilled water.* Adulteration, Section 501 (b), the article purported to be and was represented as "Water for Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard by reason of the presence of undissolved material and pyrogens; and the difference in quality and purity of the article from the official standard was not plainly stated, or stated at all, on its label.

Solution anterior pituitary and ovarian extract. Adulteration, Section 501 (b), the purity and quality of the articles fell below that which they purported and were represented to possess. They purported and were represented to be of a purity and quality suitable and appropriate for intramuscular injection and use, which use requires a sterile product. The articles were not of such purity or quality, since they were not sterile and were contaminated with living micro-organisms.

Ampuls of sodium iodide. Adulteration, Section 501 (b), the article purported to be and was represented as "Ampuls of Sodium Iodide," a drug the

*See also Nos. 2547, 2548 (veterinary preparations).

name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the official standard since it contained undissolved material; and the difference in quality and purity of the article from the official standard was not plainly stated, or stated at all, on its label.

DISPOSITION: June 24, 1948. A plea of guilty was entered on behalf of the corporation to all 4 counts of the information, and a plea of guilty was entered by the individual to count 1 of the information relating to the triple distilled water. The corporation was fined \$250 on each of the 4 counts; the individual was fined \$800 on count 1 and placed on probation for two years. Counts 2, 3, and 4 of the information were dismissed with respect to the individual.

2511. Adulteration of phenobarbital tablets and misbranding of nicotinic acid tablets and sodium iodide solution. U. S. v. California Pharmacal Co., Augustin J. Bellport, Jr., and Herbert C. Skinner. Pleas of nolo contendere. Fine of \$750 against company. Imposition of sentence against individual defendants suspended for two years and these defendants placed on probation. (F. D. C. No. 24270. Sample Nos. 18410-K, 18413-K, 18416-K.)

INFORMATION FILED: June 28, 1948, Southern District of California, against the California Pharmacal Co., a corporation, Los Angeles, Calif., and Augustin J. Bellport, Jr., president, and Herbert C. Skinner, vice-president.

ALLEGED SHIPMENT: On or about January 7, February 7, and September 9, 1947, from the State of California into the State of Ohio.

NATURE OF CHARGE: *Phenobarbital tablets.* Adulteration, Section 501 (b), the article purported to be and was represented as "Phenobarbital Tablets," a drug the name of which is recognized in the United States Pharmacopoeia, and its strength differed from the official standard since it contained more than 106 percent of the labeled amount of phenobarbital, the maximum permitted by the standard; and its difference in strength from the standard was not plainly stated, or stated at all, on its labeling.

Nicotinic acid tablets. Misbranding, Section 502 (a), the label statement "C. T. Nicotinic Acid 50 mg." was false and misleading. This statement represented and suggested that each tablet of the article contained 50 milligrams of nicotinic acid, whereas each tablet of the article contained less than 50 milligrams of nicotinic acid.

Sodium iodide solution. Misbranding, Section 502 (a), the label statement "Sodium Iodide 10% * * * Each 10cc contains 15.5 grains (1.0 gm.) of Sodium Iodide" was false and misleading. This statement represented and suggested that 10 cc. of the article contained 15.5 grains or 1 gram of sodium iodide, whereas 10 cc. of the article contained less than 15.5 grains or 1 gram of sodium iodide.

DISPOSITION: August 9, 1948. Pleas of nolo contendere having been entered, the court imposed a fine of \$750 against the corporation and suspended the imposition of sentence against the individuals for 2 years and placed them on probation.

2512. Adulteration and misbranding of Uarginin tablets. U. S. v. Grisard Laboratories, Inc. Plea of guilty. Fine of \$200 and costs. (F. D. C. No. 23264. Sample No. 83102-H.)

INFORMATION FILED: December 23, 1947, Eastern District of Tennessee, against Grisard Laboratories, Inc., Winchester, Tenn.

ALLEGED SHIPMENT: On or about March 3, 1947, from the State of Tennessee into the State of Kentucky.

LABEL, IN PART: "Tablets Salicyline No. 2. Enteric Coated. Kendall." Squill."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, in that each tablet of the drug was represented to contain an amount of the cardio-active glycosides of squill equivalent in potency to 2.5 "cat units" of digitalis, as determined by the test for tincture of digitalis set forth in the United States Pharmacopoeia, Twelfth Revision, whereas the article possessed a potency equivalent to not more than 1.55 "cat units" of digitalis, which was not more than 62 percent of the declared potency.

Misbranding, Section 502 (a), the label statements (carton) "Contains Two Of The Cardio-Active Glycosides Of Squill * * * Standardized by the U. S. P. XII Cat Method. Each tablet * * * Is Equivalent To 2.5 Cat